UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,261	04/10/2006	Kenya Shitara	Q105979	9631

65565 7590 08/17/2009

SUGHRUE-265550
2100 PENNSYLVANIA AVE. NW
WASHINGTON, DC 20037-3213

EXAMINER	
DAHLE, CHUN WU	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
08/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,261	SHITARA ET AL.	
	Examiner	Art Unit	
	CHUN DAHLE	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2009 and 25 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 13-39* is/are pending in the application.

4a) Of the above claim(s) *13,17-19,21-35,38 and 39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6, 14-16, 20, 36, and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :04/10/2006, 10/15/2007, and 12/14/2007.

DETAILED ACTION

1. Applicant's election without traverse of Group I (drawn to a fusion protein) filed on March 3, 2009, is acknowledged.

Applicant's species election of a soluble TNF receptor II in the reply filed on June 25, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 7-12 have been canceled.

Claims 1-6 and 13-39 are pending.

Claims 13, 17-19, 21-35, 38, and 39 have been withdrawn from further consideration, under 37 CFR 1.142(b) as being drawn to nonelected invention.

Claims 1-6, 14-16, 20, 36, and 37 are currently under consideration as being read on the elected invention of a fusion protein of a soluble TNF receptor II.

2. Claim 20 is objected to for following informalities:

Claim 20 recites "wherein the fusion protein composition is a dimer". It is not clear whether the fusion protein is a dimer or the composition is a dimer. Applicant is required to clarify this matter.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 36 recites the limitation "purifying the antibody from the culture" in line 4. There is insufficient antecedent basis for this limitation in the claim. Claim 36 recites "fusion protein" not "the antibody".

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 16 is drawn to a fusion protein produced by FERM BP-8499.

It is apparent that the hybridoma FERM BP-8499 is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, a deposit of the hybridoma, which produces this antibody, may satisfy first paragraph. See 37 CFR 1.801-1.809.

It is noted that FERM BP-8499 is deposited with International Patent Organism Depositary, National Institute of Advanced Industrial Science and Technology, Central 6, 1, Higashi 1-chome, Tsukuba-shi, Ibaraki, Japan, on Sep. 30, 2003, before the filing of the instant application (April 10, 2006) (e.g. see page 58 of instant specification). The depository is an acceptable international depository authority under 37 CFR 1.803 (see

MPEP 2405).

If the deposit has been made under the terms of the Budapest Treaty, an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the hybridoma has been deposited under the Budapest Treaty and that the hybridoma *will be irrevocably and without restriction or condition released to the public upon the issuance of a patent* would satisfy the deposit requirement made herein. See 37 CFR 1.808. Further, the record must be clear that the deposit will be maintained in a public depository for a period of 30 years after the date of deposit or 5 years after the last request for a sample *or for the enforceable life of the patent whichever is longer*. See 37 CFR 1.806.

If the deposit has not been made under the Budapest treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature must be made, stating that the deposit has been made at an acceptable depository and that the criteria set forth in 37 CFR 1.801-1.809, have been met.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-6, 20, 36, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Kanda et al. (US 2003/0115614).

Kanda et al. teach an antibody or a fusion protein composition and a medicament thereof comprising an antibody with an Fc region wherein the Fc region comprises complex type N-glycoside-linked sugar chains having a structure in which fucose is not

bound to N-acetylglucosamine in the reducing end in the sugar chain (e.g. see paragraphs [0240], [0258] and claims 41 and 54-56). Kanda et al. further teach said Fc region can be of human IgG1 subclass comprising a hinge region, a CH2 and a CH3 region (e.g. see paragraphs [0245]-[0258]). Furthermore, Kanda et al. teach said fusion protein can be a dimer (e.g. see paragraph [0257]). Moreover, Kanda et al. teach that said fusion protein exhibits enhanced effector function including antibody-dependent cell mediated cytotoxicity (ADCC) (e.g. see paragraphs [0262]-[0264]). In addition, Kanda et al. teach that said fusion protein or antibody can be produced by a host cells that are transformed with DNA encoding the fusion protein or antibody following with purifying the protein or antibody from the culture medium (e.g. see claims 1-20).

Therefore, the reference teachings anticipate the claimed invention.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Presta (US 2003/0157108) in view of Jacobs et al. (US Patent 5,605,690).

Presta teaches immunoadhesin, e.g. soluble TNFR combined with IgG Fc region, can be used as therapeutics to treat human diseases by blocking ligand receptor interaction and recruit the immune system effector cells to kill target cells (e.g. see paragraphs [0008]-[0009] and [0352]-[0374]). Presta further teaches glycoproteins including immunoadhesins comprising Fc region wherein the Fc region comprises complex sugar structure that lacks fucose (e.g. see SUMMARY OF THE INVENTION on pages 4-5). Thus, the prior art's glycoproteins comprises Fc region with N-glycoside linked sugar in which fucose is not bound to N-acetylglucosamine in the reducing end in the sugar chains. Furthermore, Presta teaches that said glycoproteins comprising said N-linked sugar structures exhibits superior affinity to FcγRIII (F158) and enhanced ADCC effect than glycoproteins with fucose (e.g. see paragraph [0042])/

The reference teachings differ from the claimed invention by not describing soluble TNFR II comprising SEQ ID NO:64.

Jacobs et al. teach dimerized soluble TNF receptor conjugated with human IgG1 Fc region (e.g. see Figures 1 and 2 and claim 1). The prior art soluble TNF receptor is 100% identical in amino acid sequence to the instant SEQ ID NO:64 recited in claim 15 (see sequence alignment attached to this Office Action).

It would thus be obvious to one of skill in the art at the time of the invention to combine the teachings of Presta with Jacobs et al. to make soluble TNFRII-Fc protein with N-glycan sugar structures in which fucose is not bound to N-acetylglucosamine because al the claimed elements were known in the prior art and one of skilled artisan could have combined the elements by known methods taught by Presta with no change in their respective functions, and the combination would have yielded predictable results. Further, a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention for enhanced ADCC effect of the soluble TNFRII-Fc and there would have been a reasonable expectation of success.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Dahle whose telephone number is 571-272-8142. The examiner can normally be reached on 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Ram Shukla can be reached 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Chun Dahle/
Examiner, Art Unit 1644